203. As set forth above, AstraZeneca's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

204. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca and (ii) provided the New Jersey Doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

205. The Aventis Group has engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated May 4, 2000 to the CEO of Behring, U.S. Rep. Thomas J. Bliley states:

> The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was $42.21. The OIG further estimated that the actual wholesale price of this drug was $16.12 and the highest available wholesale price that the OIG was able to identify was $32.11.

206. The government's investigation revealed similar inflated pricing implemented by The Aventis Group with respect to the injectable form of Anzemet®. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Hoechst:

> The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form

> of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

NDC No:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	$124.90	$70.00	Represented price 78% higher than true wholesale price.

207. The government investigation further revealed that the Aventis Group's fraudulent AWP scheme gave them the intended advantage over their competitors. An internal GlaxoWellcome, Inc. memo describes some of the effects:

> GLAXO: "There is a decline in Zofran [Glaxo's competing product] usage at Louisiana Oncology in Baton Rouge, Louisiana. Kevin Turner …has seen a drastic decline in Zofran usage at this clinic over the last few months. The reason for this decline is strictly a reimbursement issue. This clinic has started using Anzemet because it is more profitable. Kevin has learned that this clinic is buying Anzemet for $58.00 for a 100 mg vial, which gives them a $84.29 profit from Medicare. They are buying a 40 mg vial of Zofran for $145.28. If they use 32 mg of Zofran, which is $3.63 per mg, this will net this clinic $69.60 from Medicare reimbursement. Clearly Anzemet has a reimbursement advantage over Zofran…."

208. The government's investigation has uncovered substantial evidence that the Aventis Group's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 15 instances where the published AWPs for drugs manufactured by the Aventis Group were substantially higher than the actual prices listed by wholesalers.

209. The chart below sets forth four examples where the Aventis Group deliberately inflated AWPs that it reported for Aventis Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the Aventis Group in the 2001 *Red Book*.

Drug	The Aventis Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Dolasetron Mesylate (Anzemet)	$166.50	$74.08	$92.42	125%
Factor VIII/Bioclate	$1.25	$.91	$.34	37%
Factor VIII/Helixate	$1.18	$.78	$.40	51%
Immune Globulin (Gammar)	$400.00	$296.67	$103.33	35%

210. The OIG (*see* OEI-03-00-00310) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet® had a Medicare Median of $14.82 and a Catalog Median of $8.29, resulting in a spread of 78.76%; and (iii) a 20 mg dose of Taxotere® had a Medicare Median of $283.65 and a Catalog Median of $8.29, resulting in a spread of 18.75%.

211. As set forth above, the Aventis Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

E. Baxter

212. Baxter has engaged in an ongoing deliberate scheme to inflate AWPs in order to increase the market share of its products. Baxter's AWP scheme is widespread and the government investigation has documented substantially inflated AWPs associated with Baxter.

213. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWPs was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that Homecare companies that reimburse based on AWP make

a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWPs.[2]

214. Another Baxter document explains the basis of the AWP scheme:

> The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.

215. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

216. In a report published by DHHS, the DOJ documented at least 41 instances where the published AWPs for drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers.

217. The chart below sets forth four examples where Baxter deliberately inflated AWPs that it reported for Baxter drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

Drug in Lowest Dosage Form	**Baxter's 2001 *Red Book* AWP**	**DOJ Determined Actual AWP**	**Difference**	**Percentage Spread**
Dextrose	$928.51	$2.25	$926.26	41,167%
Dextrose Sodium Chloride	$357.69	$2.93	$354.76	12,108%
Sodium Chloride	$928.51	$1.71	$926.80	54,199%

[2] Stark 9/28/00 letter, Exh. 3.

[3] Bliley 9/25/00 letter, Exh. 6.

Drug in Lowest Dosage Form	Baxter's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Factor VIII	$1.28	$.92	$.36	39%

218. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

> BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the $.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the $.13 reduction in price . . . free product given to achieve overall price reduction."

219. As set forth above, Baxter's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

F. Bayer

220. Bayer has engaged in an ongoing deliberate scheme to inflate AWPs. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer documents reveal Bayer's participation in a scheme to artificially inflate the AWP's for their products and to market the spread:

> BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

221. Bayer, which recently was the subject of an investigation by the DOJ, agreed to settle claims asserted by the U.S. government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

> The government's investigation of the allegations...revealed that [Bayer] beginning in the early 1990s falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling the product to doctors at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit from reimbursement paid to them by the government.
>
> The Bayer AWPs, at issue in the investigation, involved several of Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.
>
> The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also has the effect of discouraging market competition from manufacturers that do not inflate AWPs as a way of inducing doctors to purchase their products.

222. The government's investigation has uncovered substantial evidence that Bayer's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 10 instances where the published AWPs for drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers.

223. The chart below sets forth two examples where Bayer deliberately inflated AWPs that it reported for Bayer drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Bayer in the 2001 *Red Book*.

Drug	**Bayer's 2001 *Red Book* AWP**	**DOJ Determined Actual AWP**	**Difference**	**Spread**
Immune Globulin	$450.00	$362.50	$87.50	24%
Factor VIII	$0.92	$0.42	$0.50	119%

224. In a DHHS OIG report (*see* OEI-03-00-00310), the government also discovered that the AWP for all immune globulin pharmaceuticals of a dosage of 5g, including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 Red Book), were over inflated by an average spread of 32.21%.

225. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

226. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

> BAYER: "I have been told that our present Kogenate price, $.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of $.60 to $.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

227. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide the state and federal governments with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

228. As set forth above, Bayer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice"

rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

G. The Boehringer Group

229. The Boehringer Group has engaged in an ongoing deliberate scheme to inflate AWPs in order to increase the market share of its products. Although each of the injectable form of the drugs marketed by the Boehringer Group is also available from other pharmaceutical manufacturers and are not brand name pharmaceuticals, the government's investigation has uncovered substantial evidence of the Boehringer Group's fraudulent pricing practices with respect to its generic pharmaceuticals.

230. The Boehringer Group's AWP Scheme is widespread and the government investigation has documented substantially inflated AWPs associated with the Boehringer Group. For example, in a report published by DHHS, the DOJ documented at least 32 instances where the published AWPs for injectable pharmaceuticals manufactured and marketed by the Boehringer Group were substantially higher than the actual prices listed by wholesalers.

231. The chart below sets forth nine examples where the Boehringer Group deliberately inflated AWPs that it reported for Boehringer Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the Boehringer Group in the 2001 *Red Book*.

Drug	The Boehringer Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	$ 528.00	$ 207.00	$ 321.00	155%
Amikacin Sulfate	$ 437.50	$ 65.33	$ 372.17	570%
Mitomycin	$ 128.05	$ 51.83	$ 76.22	147%
Cytarabine	$ 62.50	$ 3.55	$ 58.95	1,661%
Doxorubicin HCL	$ 945.98	$ 139.75	$ 806.23	577%
Etoposide	$ 110.00	$ 8.45	$ 101.55	1,202%
Leucovorin Calcium	$ 184.40	$ 2.76	$ 181.64	6,581%

Drug	The Boehringer Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Methotrexate Sodium	$ 68.80	$ 2.63	$ 66.17	2,516%
Vinblastine Sulfate	$ 212.50	$ 8.19	$ 204.31	2,495%

232. As set forth above, the Boehringer Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

H. Braun

233. Braun has engaged in an ongoing deliberate scheme to inflate AWPs in order to increase the market share of its products. Although each of the intravenous solutions marketed by Braun is also available from other pharmaceutical manufacturers and are not brand name pharmaceuticals, the government's investigation has uncovered substantial evidence of Braun's fraudulent practices with respect to certain generic pharmaceuticals.

234. Braun's AWP scheme is widespread and the government investigation has documented substantially inflated AWPs associated with Braun. For example, in a report published by DHHS, the DOJ documented at least 23 instances where the published AWPs for intravenous solutions manufactured and marketed by Braun were substantially higher than the actual prices listed by wholesalers.

235. The chart below sets forth three examples where Braun deliberately inflated AWPs that it reported for Braun drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Braun in the 2001 *Red Book*.

Drug	Braun's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Dextrose	$11.28	$1.61	$9.67	601%
Dextrose Sodium Chloride	$11.34	$1.89	$9.45	500%
Sodium Chloride	$11.33	$1.49	$9.84	660%

236. As set forth above, Braun's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

I. The BMS Group (Bristol-Myers, OTN and Apothecon)

237. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWPs. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWPs for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

238. The chart below sets forth five examples where the BMS Group deliberately inflated AWPs that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	**Manufacturer**	**BMS's 2001 *Red Book* AWP**	**DOJ Determined Actual AWP**	**Difference**	**Percentage Spread**
Amikacin Sulfate	Apothecon	$32.89	$17.31	$15.58	90%
Amphotercin B	Apothecon	$17.84	$6.20	$11.64	188%
Bleomycin Sulfate	BMS	$609.20	$509.29	$99.91	20%
Cyclophospamide	BMS	$102.89	$45.83	$57.06	125%
Etoposide (Vepesid)	BMS	$136.49	$34.30	$102.19	298%

239. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWPs – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated $941 million in revenue for the BMS Group in 1997, and Carboplatin generated $702 million in revenue in 2001.

240. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

a. In the 2000 edition of the *Red Book*, BMS reported an AWP of $1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only $70.00.

b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from $276.29 to $304.60, while the actual cost to physicians declined from $224.22 to $140.00, resulting in a spread of $164.60 in 1998

241. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

242. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

> The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

243. While the BMS Group and other Defendants have placed the blame for setting published AWPs on the publications in which the AWPs are contained, another BMS Group document demonstrates that publications reporting AWPs had no discretion to set AWPs, and instead published verbatim the prices reported by the BMS Group and other defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

> Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

244. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

245. As set forth above, the BMS Group's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

J. Dey

246. Dey has engaged in an ongoing deliberate scheme to inflate AWPs. Although one of the drugs Dey sells, albuterol sulfate, is also available from other pharmaceutical manufacturers, the government's investigation has uncovered substantial evidence of Dey's fraudulent pricing practices with respect to this drug.

247. Albuterol sulfate, was a focus of the federal government's investigation into AWP inflation. OIG found that "Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price" and that "Medicare and its beneficiaries would save between $226 million and $245 million a year if albuterol were reimbursed at prices available to suppliers." See "Excessive Medicare Reimbursement for Albuterol," OEI-03-01-00410, March 2002.

248. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was $0.42. However the actual wholesale price was $0.15, and the highest available wholesale price was $0.21.

249. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. *See* GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

250. The government's investigation has uncovered substantial evidence that Dey's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 15 instances where the published AWPs for drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers.

251. The chart below sets forth several drugs for which Dey reported inflated AWPs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	**2001 *Red Book* AWP**	**DOJ Determined AWP**	**Difference**	**Percentage Spread**
Acetylcysteine	$59.88	$25.80	$34.08	132%
Albuterol Sulfate	$30.25	$9.17	$21.08	230%
Cromolyn Sodium	$42.00	$23.01	$18.99	82%
Metaproterenol Sulfate	$30.75	$11.29	$19.46	172%

252. As part of the scheme, Dey regularly manipulated the spread by changing either the AWP or the actual sales price for its drugs. Thus, Dey's spread for albuterol sulfate drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was $32.30. McKesson's wholesale price for the drug was $25.45 (a spread of $ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to $30.25, while McKesson's

wholesale price had plummeted to $10.00 (a spread of $20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

253. The federal government is not the only entity to investigate Dey's scheme to inflate AWPs. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWPs, both state's Medicaid programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid $13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only $8.7 million -- an overcharge of $5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

254. As set forth above, Dey's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

K. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

255. The Fujisawa Group has engaged in an ongoing deliberate scheme to inflate AWPs. An internal marketing memo references its blatant manipulation of the AWP:

> Many thanks to Rick and Brace for adjusting the AWP on the five gram Vanco [Vancomycin Hydrochloride]. This should lead to more business . . . I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at $1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is $163 and their contract is $30 and if our AWP is $162 we will have to be at least $29 to have the same spread. Follow?

See letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America.

256. The government's investigation has uncovered substantial evidence that the Fujisawa Group's fraudulent practices are widespread. For example, in a report published by

DHHS, the DOJ documented at least 35 instances where the published AWPs for drugs manufactured by the Fujisawa Group's were substantially higher than the actual prices listed by wholesalers.

257. The chart below sets forth six drugs for which the Fujisawa Group reported inflated AWPs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by The Fujisawa Group.

Drug	The Fujisawa Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	$565.10[4]	$371.50	$193.60	52%
Dexamethasone Sodium Phosphate	$1.04[5]	$.66	$.38	58%
Fluorouracil	$2.87[6]	$1.20	$1.67	139%
Gentamacin Sulfate	$12.64	$5.40	$7.24	134%
Pentamidine Isethionate	$98.75	$36.00	$62.75	174%
Vancomycin Hydrochloride	$10.97[7]	$7.00	$3.97	57%

258. As set forth above, the Fujisawa Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

L. The GSK Group

259. The GSK Group has engaged in an ongoing deliberate scheme to inflate AWPs and to market the spread to increase the sales of its products. For example, in a report published by DHHS, the DOJ documented at least five instances where the published AWPs for drugs manufactured by the GSK Group or its related entities were substantially higher than the actual prices listed by wholesalers.

[4] Calculation based on the AWP listed in the 1998 *Red Book*.

[5] Calculation based on the AWP listed in the 1998 *Red Book*.

[6] Calculation based on the AWP listed in the 1998 *Red Book*.

[7] Calculation based on the AWP listed in the 1998 *Red Book*.

260. The chart below sets forth examples of drugs for which the GSK Group reported inflated AWPs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the GSK Group in the 2001 *Red Book*.

Drug	GSK 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Ondanestron (Zofran)	$128.24	$22.61	$101.63	450%
Granisetron (Kytril)	$195.20	$139.04	56.16	40%

261. Perhaps the most flagrant example of the GSK Group's fraudulent manipulation of AWPs is found in the documents relating to Glaxo's Zofran® and SKB's Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for prescribers; not over which product was better for patients.

1. Glaxo's Zofran®

262. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

> By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by $_____ in reimbursement as well as paying no upcharges for the bag or admixing

263. A follow-up internal Glaxo memo, dated October 27, 1994, entitled "Zofran Pricing Recommendation," states: "Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP." The memo later notes that "Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement."

264. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran's spread "to balance the reimbursement spread which currently exists between Zofran and the market in which it competes. . . ." The pricing options considered for increasing the "spread" for Zofran® included:

Recommendation #1

. 4.5% price increase	$178.97 to $187.02
. Increase AWP	16 2/3% to 20% $214.76 to $233.78 (8.5%)
. 3%Wholesaler (chargeback)	$187.02 to $172.92
Rebate (11/14/94 - 1/31/95)	$179.92 to $167.31 (rebate)

265. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

> The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

266. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

Option 1:	Decrease the purchase price of Kytril
Option 2:	Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than $52.00.

267. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to $233.02 in January of 1995. This was discussed in an October 27,

1994 memo entitled "Zofran Pricing Recommendation" and further discussed at a Glaxo pricing committee meeting on November 4, 1994.

268. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

> Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at $233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

269. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

> I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

270. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

> If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:
>
> Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran-perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

> *If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.*
>
> Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? *What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government*? How will this new pricing structure compare with costs in other countries?
>
> *Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?* (Emphasis added.)

271. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

> Convenient
> Costs Less Than Vial
> Higher AWP
> Better Reimbursement

272. Other internal Glaxo documents directly compared the "Profit Per Dose" and "Profit as %" and "Profit Per Vial" of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included "early pay disc" and "rebates" and "incentive."

273. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled "Profit Maximization – It's In the Bag." This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo's marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran	$110.41	$195.00	84.59	$13,957,350	76.6%

3mg bag					
Kytril 1 mg vial	$102.73	$175.00	72.27	$11,924,000	70.3%

274. Another Glaxo document entitled "Profit Maximization – Continued" reflects how much "Total Revenue Potential" there was for using Zofran® because of the large spread between the "cost" and "reimbursement" for various Zofran® products.

275. An internal SKB document further acknowledges Glaxo's attempts to use and market the spread and its effects on the Class:

> As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of "up-dosing" rather than efficacy of Zofran. *Though physicians have certainly benefited financially from such tactics, it is costing 3rd party payers and patients more for medication.* (Emphasis added.)

276. In a September 27, 2000 article in *USA Today,* Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually "representative of actual prices." Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated "We didn't want to put ourselves at a price disadvantage." Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo's sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP.

2. SKB's Kytril

277. According to its internal documents (and prior to selling Kytril®'s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

> In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.

* * *

> From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

278. Internal SKB documents reveal how it marketed the spread. One internal document entitled "Price Comparison of Kytril and Zofran for Reimbursement" discussed how much additional revenue and "spread per patient" a medical provider would make by using Kytril® due to its larger spread. It stated:

> Kytril reimbursement for 5 patients treated $540.00 - Kytril 6 treated patients $423.12
>
> Difference = $117.00 every 6 patients.
>
> Use 5h3 5 times a day = $2,340.00 month. $28,000.00 a year more!

279. Other internal SKB documents entitled "Cost v. Profit" and "Kytril Profit Model" compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

280. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

> We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

281. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of

4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients."

282. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug.

3. General Counsel Correspondence between Glaxo and SKB

283. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

284. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of "several issues pertaining to the advertising and marketing of Kytril":

> Glaxo's sales representatives have encountered a substantial amount of what appear to be "homemade" Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.
>
> . . . .
>
> In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their "profits" from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate."

285. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr.

Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

> Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. *The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.* (Emphasis added.) Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. *Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.* (Emphasis added.)

286. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran. However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

> It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.

* * *

> It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.
>
> Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

287. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Class.

288. As set forth above, the GSK Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

M. Immunex

289. Immunex has been engaged in an ongoing deliberate scheme to inflate AWPs and has deliberately attempted to hide its participation in the scheme. In a letter dated September 28, 2000, to the president of a national pharmaceutical trade group, Representative Stark exposed Immunex's scheme, stating:

> The documents further expose the fact that certain of your members deliberately concealed and misrepresented the source of AWPs:
>
> In a 1996 Barron's article entitled "Hooked On Drugs," the following quote from Immunex appeared (Composite Exhibit #11):
>
> IMMUNEX: "But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. The drug manufacturers have no control over the AWPs published . . .," says spokeswoman, Valerie Dowell. (IMNX003079)
>
> However, Immunex's own internal documents indisputably establish the knowledge of the origin of their AWPs and their active concealment:
>
> LETTER FROM RED BOOK TO IMMUNEX:
>
> Kathleen Stamm
> Immunex Corporation . . .

Dear Kathleen:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system. The price changes that were effective January 3, 1996 were posted in our system on January 5, 1996. I have enclosed an updated copy of your Red Book listing for your files. If there is anything else I could help you with do not hesitate to call.

Sincerely,
Lisa Brandt,
Red Book Data Analyst

290. The government's investigation has uncovered substantial evidence that Immunex's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 7 instances where the published AWPs for drugs manufactured by Immunex were substantially higher than the actual prices listed by wholesalers.

291. The chart below sets forth two examples where Immunex deliberately inflated AWPs that it reported for Immunex drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

Drug	2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Leucovorin Calcium	$137.94	$14.58	$123.36	846%
Methotrexate Sodium	$20.48	$7.10	$13.38	188%

292. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare program and compared Medicare's payments with the prices available to the physician and supplier communities. For mitoxane hydrochloride, sold by Immunex under the brand name Novantrone®, the DHHS found that Medicare paid $172.81, while the actual average wholesale price was $142.40, resulting in a spread of 21.36%.